

## **REMARKS**

### **In the Specification:**

Applicants have herein amended the paragraph on page 16 beginning at line 7 and ending at line 17 by providing the generic terminology for the proprietary mark, Avogel<sup>®</sup>. Applicants note that the proprietary Avogel<sup>®</sup> mark also is used at pages 29, 30, and 31 of the specification. However, Applicants respectfully submit that the generic terminology provided at the amended paragraph on page 16 is sufficient to ensure avoidance of any use of the mark that might adversely affect its validity.

Applicant have overcome the objection to the specification and respectfully request it be withdrawn.

### **In the Claims:**

Claims 82, 87, 92, 93, 101, 102, 107, 108, and 110 are cancelled herein without disclaimer or prejudice to pursuing the invention of those claims in continuing or divisional applications.

Claims 80, 89, and 103 are amended herein. Claim 80 is amended to clarify that the claimed method is directed at topical administration, and to clarify that the claimed method involves use of a composition consisting essentially of (i) a pharmaceutically acceptable carrier, and (ii) at least one non-steroidal anti-inflammatory agent, wherein administering the at least one non-steroidal anti-inflammatory agent in an amount ranging from about 0.1 to about 10 percent by weight of the pharmaceutically acceptable carrier reduces the size or improves the appearance of a closed wound, wherein the closed wound has an intact epithelial surface. In addition, claim 80 is amended to clarify that the closed wound treated by the claimed method consists of a normal scar, a hypertrophic scar, a Dupuytren's contracture, a Peyronnie's Disease, a reactive scar, an excessive post-operative scar, or a fibrotic scar. No new matter is added by amendment of claim 80 and support for claim 80 as amended may be found throughout the specification, including at page 6, lines 18-20; pages 7-8; page 11, line

28-page 12, line 2; page 12, lines 9-13, lines 19-29; page 13, lines 1-21, lines 25-29; page 14, lines 1-3; and page 25, lines 12-14.

Claim 89 is amended to clarify that the pharmaceutically acceptable carrier of claim 80 may be a thermal insulating material. No new matter is added by this amendment and support for claim 89 as amended may be found throughout the specification, including at page 12, line 29 – page 13, lines 1-5; page 14, lines 1-5; page 14, lines 29-30-page 15, lines 1-3; and page 17, lines 11-19; .

Claim 103 is amended to clarify that the claimed kit is directed at treating a closed wound that has an intact epithelial surface, wherein the closed wound is selected from the group consisting of a normal scar, a hypertrophic scar, a Dupuytren's contracture, a Peyronnie's Disease, a reactive scar, an excessive post-operative scar, or a fibrotic scar. In addition, claim 103 is amended to clarify that the kit includes a sterile solution for mixing the at least one non-steroidal anti-inflammatory agent and the pharmaceutically acceptable carrier such that the non-steroidal anti-inflammatory agent is present in an amount ranging from about 0.1 to about 10 percent by weight of the pharmaceutically acceptable carrier. No new matter is added by amendment of claim 103 and support for claim 103 as amended may be found throughout the specification, including at page 6, lines 18-20; pages 7-8; page 25, lines 12-14; and pages 26-28.

New claims 111-118 are added herein. New claim 111 is directed to the kit of claim 103, wherein the pharmaceutically acceptable carrier comprises a polyethylene glycol in combination with water. No new matter is added by new claim 111 and support for new claim 111 may be found throughout the specification, including at page 27, lines 12-17 and page 28, lines 6-16.

New claim 112 is directed to a method for reducing the size or improving the appearance of a closed wound that involves topically administering a composition consisting essentially of: (i) a pharmaceutically acceptable carrier; (ii) at least one of an anti-irritant, an anti-microbial, an anti-prurient agent, and a deodorant agent; and (iii) at least one non-steroidal anti-inflammatory agent, wherein administering the non-steroidal

anti-inflammatory agent in an amount ranging from about 0.1 to about 10 percent by weight of the pharmaceutically acceptable carrier reduces the size or improves the appearance of the closed wound. The closed wound of new claim 112 has an intact epithelial surface and is selected from the group consisting of a wound caused by laceration; a wound caused by avulsion; a wound caused by burn; a wound caused by radiation; a wound caused by chemical facial peel; and a wound caused by accident, wherein the closed wound further consists of a normal scar, a hypertrophic scar, a Dupuytren's contracture, a Peyronnie's Disease, a reactive scar, an excessive post-operative scar or a fibrotic scar. No new matter is added by new claim 112 and support for this claim may be found throughout the specification, including at page 6, lines 18-20; pages 7-8; page 11, line 28-page 12, line 2; page 12, lines 9-13, lines 19-29; page 13, lines 1-21, lines 25-29; page 14, lines 1-3; and page 25, lines 12-14.

New claim 113 depends from new claim 112 and further specifies that the anti-irritant or anti-prurient agent is selected from the group consisting of glyceryl monooleate, diphenhydramine, calamine, and a C<sub>3</sub>-C<sub>4</sub> diol and wherein the deodorant or antimicrobial agent is selected from the group consisting of aluminum zirconium trichlorohydrate, and zinc acetate. No new matter is added by new claim 113 and support for this claim may be found throughout the specification, including at page 3, lines 29-30-page 4; page 12, lines 20-25; page 17, lines 1-5; page 18, lines 26-27.

New claim 114 also depends from new claim 112 and further specifies that the pharmaceutically acceptable carrier is a thermal insulating material. No new matter is added by new claim 114 and support for this claim may be found throughout the specification, including at page 12, line 29 – page 13, lines 1-5; page 14, lines 1-5; page 14, lines 29-30-page 15, lines 1-3; and page 17, lines 11-19;.

New claim 115 depends from claim 114 and further specifies that the thermal insulating material is selected from the group consisting of a gel, a hydrogel, and a sponge. No new matter is added by new claim 115 and support for this claim may be found throughout the specification, including at page 15-16.

New claim 116 is directed at a kit for reducing the size or improving the appearance of a closed wound and consists essentially of at least one of a metallic anti-microbial agent, an anti-prurient agent, a deodorant agent, at least one non-steroidal anti-inflammatory agent, a pharmaceutically acceptable carrier, and a sterile solution for mixing two or more of these. The closed wound of claim 116 is a wound with an intact epithelial surface and is caused by laceration; by avulsion; by burn; by radiation; by chemical facial peel; or by accident. The closed wound of new claim 116 further consists of a normal scar, a hypertrophic scar, a Dupuytren's contracture, a Peyronnie's Disease, a reactive scar, an excessive post-operative scar or a fibrotic scar. No new matter is added by new claim 116 and support for this claim may be found throughout the specification, including at page 6, lines 18-20; pages 7-8; page 11, line 28-page 12, line 2; page 12, lines 9-13, lines 19-29; page 13, lines 1-21, lines 25-29; page 14, lines 1-3; and page 25, lines 12-14; and pages 26-28. .

New claim 117 depends from new claim 116 and further specifies that that the anti-irritant or anti-prurient agent is selected from the group consisting of glyceryl monooleate, diphenhydramine, calamine, and a C<sub>3</sub>-C<sub>4</sub> diol and wherein the deodorant or antimicrobial agent is selected from the group consisting of aluminum zirconium trichlorohydrate, and zinc acetate. No new matter is added by new claim 117 and support for this claim may be found throughout the specification, including at page 3, lines 29-30-page 4; page 12, lines 20-25; page 17, lines 1-5; page 18, lines 26-27.

New claim 118 depends from new claim 116 and further specifies that the pharmaceutically acceptable carrier comprises a polyethylene glycol in combination with water. No new matter is added by new claim 118 and support for this claim may be found throughout the specification, including at pages page 27, lines 12-17 and page 28, lines 6-16.

## **Claim Rejections:**

### **35 U.S.C. § 112, First Paragraph**

Claims 80, 82, 87, 89, 92, 93, 101-103, and 107-110 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office action alleges that “[t]he specification as originally filed does not disclose “reducing the size of a closed wound.”

Applicants respectfully disagree and direct the Examiner’s attention to the last paragraph beginning on page 11, line 28 and continuing onto page 12. This paragraph states that “[b]y ‘improving the size and appearance of a healed wound or a scar . . . is meant . . . reducing the size of a scar.’” In addition, at page 30, the specification, discussing the results of using the claimed method to treat a scar, explains that “the treated scar was observed to reduce in size 50%.” At page 6 of the specification, lines 18-24, Applicants explain that the terms “healed wound” and “scar” include a closed wound. Therefore, Applicants respectfully disagree that the specification does not disclose reducing the size of a closed wound. This ground of rejection is improper and Applicants request it be withdrawn.

### **35 U.S.C. § 112, Second Paragraph**

Claims 80, 89, 92, 109, and 110 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

In particular, the Office action alleges that it is unclear whether the claimed method involves topical administration, oral administration, or administration by injection. To expedite prosecution and to clarify the scope of claim 80, Applicants have herein amended claim 80 to clarify that the claimed method is directed to topical administration. As stated previously, Applicants amendment of claim 80 is without prejudice or disclaimer to pursuing a method of the present invention that involves other routes of administration, including oral administration and administration by injection, in

continuing or divisional applications. Claims 89, 92, 109, and 110 each depend from claim 80.

The Office action also alleges that claim 82 is indefinite. Claim 82 is cancelled herein without prejudice or disclaimer to pursuing the invention of claim 82 in continuing and divisional applications.

Applicants respectfully submit that the claims, as clarified, are no longer indefinite and respectfully request that the Examiner withdraw this ground of rejection.

### **35 U.S.C. § 102**

Applicants respectfully submit that amended claims 80, 89, 103, 109 and new claims 111-118 are not anticipated by either JP-8-268,886 or U.S. Patent No. 6,521,271. Applicants respectfully request that rejection of the claims under 35 U.S.C. § 102 be withdrawn.

### **35 U.S.C. § 103**

Applicants respectfully submit that amended claims 80, 89, 103, 109 and new claims 111-118 are not rendered obvious by any of DE 27 07 537, JP-8-269,886 or U.S. Patent No. 6,521,271, either alone or in combination with U.S. Patent No. 5,552,162. Applicants respectfully request that this ground of rejection be withdrawn.

## CONCLUSION

Applicants believe that currently pending Claims 80, 89, 103, and 109 and new claims 111-118 are patentable. The Examiner is invited to contact the undersigned attorney for Applicants via telephone if such communication would expedite allowance of this application.

Respectfully submitted,

A handwritten signature in cursive script, reading "C. Noel Kaman", written over a horizontal line.

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